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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,477	01/14/2004	Anuja Nair	895,675-195	5834
72286	7590	05/22/2009	EXAMINER	
LEYDIG, VOIT & MAYER, LTD			SHAHRESTANI, NASIR	
TWO PRUDENTIAL PLAZA, SUITE 4900				
180 N. STETSON			ART UNIT	PAPER NUMBER
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			05/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/758,477	NAIR ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	NASIR SHAHRESTANI	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 06 March 2009.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-34 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 14 January 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>06/24/2004; 08/29/2005; 08/22/2006</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____ .



## **DETAILED ACTION**

### ***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. The specification has provided a commonly owned reference (U.S. 6,200,268) on page 6, which has not been listed within the Information Disclosure Statement.

### ***Election/Restrictions***

Upon further consideration, the previous requirement for restriction dated 06/30/2008 has been withdrawn. All pending claims have been examined.

### ***Claim Objections***

Claims 9 and 10 objected to because of the following informalities: "a group" should be "the group". Appropriate correction is required.

Claims 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim does not provide a further step to the method of claim 1.

Claims 14-19, 22-23, 25, 27-29, 32 and 34 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims do not provide further structure to the system of independent claims 13 and 26.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 21-24, 26-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the transfer function" in line 9. There is insufficient antecedent basis for this limitation in the claim.

Regarding claims 21-24, 26-34, it is unclear how a characterization application (construed to be a software application) is "electrically connected" to the database.

Furthermore, regarding claim 24, it is unclear how a display can provide the function of imaging.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1, 3-16, 18-28, 30-34** are rejected under 35 U.S.C. 103(a) as being obvious over Vince et al. (U.S. 6,200,268 B1) in view of Rex (U.S. 6,038,468).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference

under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Vince et al. teach a catheter (fig. 1) comprising at least one transducer (element 20) as well as a computing device (col. 4 lines 5-7). Vince et al. teach an ultrasonic method and system for characterizing plaque components within a vascular object (see abstract). Vince et al. further teach inserting at least a portion of a catheter into a vascular structure (col. 3 line 55); activating a transducer portion (col. 3 line 57), said activation of said transducer resulting in an ultrasound signal begin transmitted toward vascular tissue and acquiring backscatter ultrasound data from said vascular tissue (col. 3 lines 57-59).

As applicant has stated (page 2/13 under Description of Related Art), traditionally the transfer function (being estimated in the Vince et al. reference) has been determined with the catheter outside of the patient however Vince et al. do not teach the estimation of a transfer function of the inserted catheter.

Rex teaches an ultrasonic catheter localization system (see title and abstract) wherein a transfer function may be determined for each acoustic signal, once reflections of the acoustic signal from the wall of the part of the body in which the catheter head is disposed are received (col. 2 lines 7-14). With regards to claims 3 and 18, Rex further teaches providing an iterative process of model fitting (col. 2 line 25).

It would have been obvious to one of ordinary skill in the art at the time of invention to have modified Vince et al. and to have incorporated the teaching of Rex, providing the estimation of the transfer function of the inserted catheter, so that a further and more precise step of catheter localization can be achieved from backscatter data received within the vascular wall of the patient.

Regarding claims 4-6 and 19, Vince et al. further teach correction of backscatter data and wherein in order to accurately match coordinates of images, the histological image is warped to fit the contour of the IVUS image (col. 4 lines 10-32).

Regarding claims 7, 8, 11, 21, 26, 32-34, Vince et al. further teaches final signal parameters corresponding to the plaque component within a region of interest which represents the plaque content from the histology region of interest are stored in a look up table or database and correlated/characterized to the plaque content (figs. 6A and 6B) which also shows performing a fast Fourier transform of signal segments (transformation from time domain to frequency domain) and the identification/display of the segments (A1 and B1) using a database adapted to store a plurality of parameters corresponding to a plurality of vascular tissue types (see Vince et al. claim 7) and a method of characterizing a plaque component (Vince et al. claim 16).

With regards to claims 9 and 22, Vince et al. further teach that additional analysis can be performed such as spectral density and/or power spectrum analysis to provide more information regarding the signal (col. 5 lines 10-14).

Regarding claims 10 and 23, Vince et al. show that the types of plaque components which may be found in a blood vessel include collagen, calcium, necrotic areas, lipids and cholesterol (col. 4 lines 22-24).

With regards to claims 12, 16, and 25, the limitations of the claims are merely providing a duplication and repetition of the method of claim 1 and no additional structure to claim 13 and are hence an obvious addition to the method of calculation in order to provide further backscatter ultrasound data of the vasculature. As described before, Rex teaches an algorithm/application to calculated response data with regards to a transfer function.

With regards to claims 20, 30, 31, Vince et al. further teach the ultrasonic device may also be an array of transducers circumferentially positioned to cover 360 degrees where each transducer radially acquires radio frequency data from a fixed position (col. 3 lines 50-53).

Regarding claim 24, Vince et al. show that the histology image shows different tissue types with different colors which are identifiable by a trained operator (col. 4 lines 20-22).

**Claims 2, 17, 29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Vince et al. in view of Rex as applied to claims 1, 13 and 26 above, and further in view of Sieben (U.S. 5,445,155).

Vince et al. in view of Rex teach all the limitations of claims 1, 13 and 26 but do not specifically address a step filtering noise from backscattered ultrasound data.

It would have been obvious to one of ordinary skill in the art at the time of invention to have modified Vince et al. in view of Rex and to have provided the filtering of noise in

ultrasound data, being well-known in the art and exemplified by Sieben (col. 14 lines 13-25), wherein a method is employed to improve signal-noise ratio, hence providing clearer data.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NASIR SHAHRESTANI whose telephone number is (571)270-1031. The examiner can normally be reached on Mon.-Thurs: 7:30-5:00, 2nd Friday: 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/  
Primary Examiner, Art Unit 3737

/Nasir Shahrestani/  
Examiner, Art Unit 3737